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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
LAM, ANN Y	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 04/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/768,742	TERPETSCHNIG ET AL.	
	Examiner	Art Unit	
	Ann Y. Lam	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 November 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-30,33-41,83-86 and 88-90* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-30,33-41,83-86 and 88-90* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/7/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement filed November 7, 2005 fails to comply with 37 CFR 1.98(a)(2), which requires information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. (The IDS submitted November 7, 2005 indicates that the application number for that IDS is 11/204,439. Because that application number does not match the application number for this present Office action, the document in that IDS has not been considered.)

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 28-30, 33-41, 83-86 and 88-90 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 83 recites "the probe" in line 10. It is not clear that this probe is the same luminescent probe as in line 4. (The word "probe" in the claim appears to refer to the luminescent probe, but this is not clear in the claims. Additionally, it is also not clear that "the probe" in the claim is the luminescent probe because the use of the word

"probe" in the detailed description of the specification refers to a binding agent, not necessarily a luminescent probe.) For purposes of examination, "the probe" in line 10 will be interpreted to mean –the luminescent probe--.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 83, 28, 30, 37-41, 85, 89 and 90 are rejected under 35 U.S.C. 102(e) as being anticipated by Pollok et al., 6,410,255.

As to claim 83, Pollok et al. disclose a kit comprising:

an enzyme (i.e., protease, col. 25, line 9);

a luminescent probe (i.e., fluorescent moiety, col. 25, line 6) bound to a substrate (i.e., polypeptide moiety, col. 25, lines 4-6) for the enzyme ;

and a particulate mass label (i.e., solid matrix, e.g., bead, col. 25, lines 30-32) distinct from the enzyme and capable of specifically binding to the substrate or a product of the substrate produced by action of the enzyme on the substrate, but not both (col. 25, lines 30-36);

wherein a luminescence property of the probe is sensitive to binding of the mass label to the substrate or product (col. 25, lines 30-36).

As to claim 28, the probe is photoluminescent (col. 25, line 6.)

As to claim 30, the probe is bound to the substrate noncovalently (col. 20, lines 64-67.)

As to claim 37, the probe is not normally present in the sample. (The Office notes that this is a recitation of intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, such as in this case, then it meets the claim.)

As to claim 38, the mass label is not normally present in the sample (The Office notes that this is also a recitation of intended use, and the prior art structure is capable of performing the intended use.)

As to claim 39, the property of the probe is related to a rotational diffusion coefficient of the probe (col. 25, lines 30-36.)

As to claim 40, the property may be measured using a technique selected from the group consisting of polarization and light scattering (col. 25, lines 30-36).

As to claim 41, the property of the probe is related to the translational diffusion coefficient of the robe (col. 25, lines 30-36.)

As to claim 85, the particulate mass label is a bead (col. 25, line 32).

As to claim 89, the luminescence property may be measured using fluorescence polarization (col. 25, lines 30-36.)

As to claim 90, the enzyme converts the probe bound to the substrate into a probe bound to the product, wherein the mass label is capable of binding specifically to the substrate, and wherein the luminescence property of the probe is different for the probe bound to the product than for a complex of the probe, the substrate, and the mass label (col. 25, lines 30-36).

3. Claims 83 and 88 are rejected under 35 U.S.C. 102(e) as being anticipated by Nikiforov, 6,689,565.

As to claim 83, Nikiforov disclose a kit comprising:

an enzyme (306, see col. 14, line 32);

a luminescent probe bound to a substrate (302, see col. 14, line 32) for the enzyme;

and a particulate mass label (i.e., polycation, such as polyhistidine, col. 14, line 38) distinct from the enzyme and capable of specifically binding to the substrate or a product of the substrate produced by action of the enzyme on the substrate, but not both;

wherein a luminescence property of the probe is sensitive to binding of the mass label to the substrate or product (col. 14, lines 41-44).

(The Office notes that a "particulate" as described by Application in the specification on page 15 can be a macromolecule. Thus, the polycation is considered a

particulate. Also, Nikiforov teaches that the polycation is used to increase the size of the product to affect rotational diffusion rate, and thus the polycation is considered a mass label, as is consistent with Applicant's specification.)

As to claim 88, the mass label (i.e., polycation, col. 14, line 38) is capable of binding specifically to the product (col. 14, lines 37-38), and wherein the luminescence property of the probe is different for the probe bound to the substrate than for a complex of the probe, the product, and the mass label (col. 14, lines 41-44).

4. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pollok et al., 6,410,255.

Pollok et al. teach the invention substantially as claimed (see above). However, Pollok et al. do not teach that the probe is capable of having a photoluminescence lifetime that is greater than the rotational correlation time of the unbound probe and less than the rotational correlation time of the complex formed by binding of the substrate or the product to the mass label.

However Pollok et al. teach that once an optical probe is separated from the bead, this results in an increased rotational flexibility (col. 25, lines 32-36.) Pollok et al. teach that various choice of fluorescent moieties may be used (col. 7, lines 2-12.) Pollok et al. also teach that various choice of enzymes and substrates may used (col. 19, lines 18-27.) Whether the photoluminescence lifetime is greater than the rotational correlation time of the unbound probe and less than the rotational correlation time of the complex formed by binding of the substrate to the mass label depends on what

fluorescent moiety is used and what choice of enzymes and substrates are used, and Pollok et al. teach that various choices of fluorescent moieties and enzymes and substrates may be used. Moreover, the photoluminescence lifetime as claimed by Applicant appears to be an optimum or workable range. It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

5. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pollok et al., 6,410,255, in view of Zarling et al., 5,674,698.

Pollok et al. teach the invention substantially as claimed (see above). However, Pollok et al. do not teach that the mass label includes a plurality of binding moieties that bind to the substrate such that the mass label is capable of specifically binding to more than one substrate or product molecule at the same time.

Zarling et al. teach that more than one probe, such as antibodies, may be attached to a label, such as a bead, in polarization assays (col. 10, lines 53-57.) Zarling et al. teach that attachment chemistries can be employed to link the probe to the label (col. 10, lines 53-57.) It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide multiple binding moieties on the particle as taught by Zarling et al. in the Pollok et al. because Zarling et al. teach that more than one probe may be attached to a particle as an alternative to one probe per particle.

(That is, Zarling et al. teach that one probe per particle is a functional equivalent to multiple probes, and thus multiple binding moieties, per particle.)

6. Claim 84 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pollok et al., 6,410,255, in view of Kopf-Sill et al., 6,524,790.

Pollok et al. teach the invention substantially as claimed (see above). More specifically, Pollok et al. teach that the mass label is a bead (col. 25, line 32). However, Pollok et al. do not teach that the material forming the bead is glass but only teaches that the solid matrix may be a bead in general.

Kopf-Sill et al. teach that solid supports such as beads, including glass beads, are suitable supports for immobilization of assay components such as peptides (col. 34, lines 54-61). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use glass as taught by Kopf-Sill et al. as the particular material for the beads generally disclosed Pollok et al. invention because Kopf-Sill et al. teach that glass beads are suitable types of beads for immobilization of assay components such as peptides, such as the peptides in the Pollok et al. invention.

7. Claim 86 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pollok et al., 6,410,255, in view of Nicoli et al., RE33581.

Pollok et al. teach the invention substantially as claimed (see above). More specifically, Pollok et al. teach that the mass label to which the polypeptide is attached

is a solid matrix, or a bead (col. 25, line 32). However, Pollok et al. do not teach that the solid matrix may be a colloidal metal.

Nicoli et al. teach that a particularly good example of a carrier is a colloidal metal particle (sol) such as colloidal gold. Nicoli et al. teach that it is known that most macromolecules absorb strongly onto gold sols as well as other metal sols (col. 15, lines 26-30). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide colloidal metal such as colloidal gold as taught by Nicoli et al. as the solid matrix in the Pollok et al. invention because Nicoli et al. teach that colloidal metals provide the advantage of allowing most macromolecules to absorb strongly onto it, as would be desirable for more accurate results.

8. Claims 83 and 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yguerabide et al., 6,586,193, in view of Pollok et al., 6,410,255.

Yguerabide et al. disclose the invention substantially as claimed.

As to claim 83, Yguerabide et al. disclose a kit comprising:

an enzyme (col. 86, line 66 – col. 87, line 8);

and a particulate mass label distinct from the enzyme and capable of specifically binding to the substrate or a product of the substrate produced by action of the enzyme on the substrate, but not both (col. 86, line 66 – col. 87, line 8)

Yguerabide et al. however do not teach a luminescent probe bound to the substrate for the enzyme, wherein a luminescence property of the probe is sensitive to binding of the mass label to the substrate or product.

Pollok et al. however teach that polarization measurements of a fluorescent moiety attached to an enzyme substrate which is immobilized on a bead are used to measure the rate of the enzyme-substrate activity (col. 25, lines 1-12, and lines 30-36.) Pollok et al. teach that cleavage of the substrate from the bead by the enzyme results in a larger drop in fluorescence polarization because of the increased rotational flexibility of the substrate once separated from the bead (col. 25, lines 32-36.)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide attach a fluorescent moiety to the enzyme substrate as taught by Pollok et al. in the Yguerabide et al. because Pollok et al. teach that the fluorescent moiety provides a means to detect the change in polarization once the substrate-fluorescent moiety is cleaved from the bead.

As to the following claims, Yguerabide et al. teach the limitations as follows.

As to claim 34, Yguerabide et al. teach that the mass label is a first mass label, the kit further comprising a second mass label capable of specifically binding to at least one of the substrate, a complex formed by binding of the probe to the substrate, the product, and the first mass label, but not to the probe alone (col. 12, lines 30-33, col. 84, lines 26-36, and col. 87, lines 61-64). (That is, Yguerabide et al. teach that linking two or more particles together using chemical or biological cross-linking agents amplifies detection of analytes.)

As to claim 35, Yguerabide et al. teach that the second mass label is capable of specifically binding to at least two first mass labels, so that the second mass label may form crosslinks between molecules of the substrate (col. 88, lines 3-12). That is, Yguerabide et al. teach that a particle aggregate or network structure that contains many particles bound together produces a high level of intensity which is much easier to detect than one particle" (col. 88, lines 3-12).

As to claim 36, Yguerabide et al. teach that the second mass label includes at least biotin (col. 88, lines 3-12). (The Office notes that although Yguerabide et al. teach that the second mass label includes biotin indirectly, through linkage with streptavidin, the claim nevertheless read on this disclosure.)

Response to Arguments

Applicant's arguments filed November 7, 2005 have been fully considered but are moot in view of the new grounds of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Schmidt et al., 6,582,916, discloses that metal ions such as hexahistine are used as mass labels. Hansen, 5,286,452, teaches that agglutination of two particles amplifies the visibility of reactions (col. 3, lines 12-19, and col. 1, lines 36-40 and 53-56), for detection methods such as anisotropy and dynamic light scattering spectroscopy (col. 3, lines 1-5).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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